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OCT 17 2012

SECTION 5 - 510(k) Summary (21 CFR 807.92)

510(k) Number K 121344

1	Submission Owner	RH Associates LLC 257 Middle Country Rd. Smithtown, 11787 NY Phone 631-724-4664 Fax 631-360-7880		
2	Official Correspondent Contact Person	Sterling Medical Registration Daniela Levy - Regulatory Consultant 22817 Ventura Blvd#161 Woodland Hills, 91364 CA Phone 213-787-3026 Phone 213-447-5297 Web www.sterlingmedicalregistration.com		
3	Submission Date	February 2012		
4	Device Trade Name	Nu Sleep		
5	Regulation Description	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea (OSA)		
6	Classification	Device Name	:	Device, Anti-Snoring
		Product Code	:	LRK
		Regulation No	:	872.5570
		Class	:	II
		Panel	:	Dental
7	Reason for the Premarket Notification Submission		:	New Device

8 Identification of Legally Marketed Predicate Devices :

- Nu Sleep appliance is substantially equivalent to Respire Blue Series K111207; Somnomed MAS Flex S K073004; EMA K971794; in terms of intended use,

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indication for use, technological characteristics, performance and user interface.

The predicate devices are Class II medical devices.

9 Device Description :

Nu Sleep appliance is a patient specific made device for each patient which consists of two dental plates, upper and lower, made of Acrylic.

The attachment is at a 40 degree angle to enable movement of the appliances, thus patient can open and close while wearing the appliances. The appliance is open in the front and allowing the patient to inhale and exhale more air per breath.

The RH Associates obstructive sleep apnea appliance "Nu-Sleep" is offered in Hard/Soft which has a dual laminate layer that provides a soft layer on the tooth surface which is made of acrylic.

10 Intended use :

- The Nu Sleep appliance is indicated to treat mild to moderate Obstructive Sleep Apnea.

11 Performance Standards or Special Controls :

- Recognized Consensus Standard: ISO 7405:2008 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry

12 Substantial Equivalence :

Substantial Equivalent Table	**Candidate NU Sleep Device**	**Respire Blue Series (Hard/Soft Surface)**	**EMA**	**Somnomed Flex S**
510k Number		**K111207**	**K971794**	**K073004**
Company Name	**RH Associates LLC**	**Respire Medical LLC**	**Frantz Design Incorporated**	**Somnomed Inc**
Intended Use				
Intended as an intraoral device	YES	YES	YES	YES
Intended to reduce snoring or help alleviate snoring	YES	YES	YES	YES
Treatment of mild to moderate obstructive sleep apnea	YES	YES	YES	YES
Indicated for single patient multi - use	YES	YES	YES	YES
Indicated for use at home or sleep labratories	YES	YES	YES	YES
Target population - Adults patients	YES	YES	YES	YES
Prescription Device	YES	YES	YES	YES

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Design				
Rigid tray pieces	YES	YES	YES	YES
Separate tray pieces	YES	YES	YES	YES
patient specific fit for each patient	YES	YES	YES	YES
Works by mandibular advancement	YES	YES	YES	YES
Can be adjusted or refit	YES	YES	YES	YES
Placed in patient mouth each evening	YES	YES	YES	YES
Cleaned daily	YES	YES	YES	YES
Easily removed from mouth	YES	YES	YES	YES
Lower jaw adjustment using a supplied adjustment key	YES	YES	YES	YES
Upper and lower tray unhook for easy removal from mouth	YES	YES	YES	YES
Permits patients to breat through mouth	YES	YES	YES	YES
Material				
Trays constructed from molded hard acrylic and ball clasps	YES	YES	YES	NO
Trays constructed from a soft lining material adhered to a hard surface acrylic	YES	YES [No for hard]	NO	YES
Trays constructed from a heat sensitive impermissible material for fitting to teeth	NO	NO	NO	NO
Non Sterile	YES	YES	YES	YES

Summary of Equivalence: Nu Sleep appliance is substantially equivalent to Respire Blue Series K111207; Somnomed MAS Flex SK073004 and EMA K971794 devices. As similar to its predicate device Nu Sleep appliance is a patient specific made device, consists of two parts, upper and lower trays, made of acrylic.

Nu Sleep differs from both the Respire Blue and the Somnomed in that the both require a very rigged plastic to handle the forces applied to the acrylic wings. Nu Sleep utilizes stainless steel to handle the forces so that the contact position can be placed further back in the mouth.

The design differences emphasis the advantages of Nu Sleep technology. Nu Sleep shares the same technological characteristics as its predicate devices and thus, the Nu Sleep appliance is substantially equivalent to its predicate devices.

Risk Assessment performance to ensure the safety and effectiveness related to the appliances.

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Bench testing - Comparable Chemical Structure testing was conducted with Nu Sleep and its predicate devices. Test results have demonstrated the equivalent and/or similarity of Nu Sleep to its predicate devices. Thus, Nu Sleep appliance shares similarity with its predicate devices.

GPC testing was conducted in order to determine the molecular weight and the molecular weight distribution. Test results have met all acceptable criteria.

Clinical evaluation study was conducted on 31 patients, female & male, at one facility. The study observation was conducted in two stages, stage one without the appliance, stage two with the appliance. Objective criteria have been observed and have been measured, such as: total sleep, RDI, AHI, ODI, at both stages. Clinical evaluation and observation results have demonstrated the success rate of reduction of snoring and the success rate of reduction of apneic events measured by polysomnograms. Thus, Nu Sleep appliance shares similarity in the indication of use to its predicate devices.

Conclusion:

As verified by clinical and non clinical data, bench testing and substantial equivalence table, Nu Sleep appliance shares similarity with its predicated device by term of intended use, raw material and technical design. The fundamental scientific technology of the device is identical or very similar to the referenced predicate devices, thus Nu Sleep appliance is considered to be substantially equivalent to the its predicates devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 17 2012

RH Associates, Limited Liability Company
C/O Daniela Levy
Regulatory Consultant
Sterling Medical Registration
22817 Ventura Boulevard # 161
Woodland Hills, California 91364

Re: K121344
Trade/Device Name: Nu Sleep
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea
Regulatory Class: II
Product Code: LRK
Dated: September 13, 2012
Received: September 17, 2012

Dear Ms. Levy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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SECTION 4 - Indication for Use Statement

Indications for Use

Indications for Use

510(k) Number (if known): K121344

Device Name:

Nu Sleep

Indications for Use:

The Nu Sleep appliance is indicated to treat mild to moderate Obstructive Sleep Apnea.

Prescription Use _✓__ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Shaan Parmar

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K121344